PATENT
Customer No. 22,852
Attorney Docket No. 07552-0055-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Bernard BENE et al.	)	Group Art Unit: 1797
	)	
Application No.: 10/526,498	)	Examiner: Bass, Dirk R.
	)	
Filed: September 29, 2005	)	Confirmation No.: 7337
	)	
For: CONTROL APPARATUS AND CONTROL METHOD FOR A BLOOD TREATMENT EQUIPMENT	)	

Mail Stop Appeal Brief--Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed June 16, 2010, and further to Board Rule 41.37, Appellant presents this brief and encloses herewith the fee of $540.00 required under 37 C.F.R. § 41.20(b)(2).

This Appeal Brief is being filed concurrently with a petition for an Extension of Time for one (1) month and the appropriate fee.

This Appeal responds to the December 17, 2009, final rejection of claims 4-17, 20-44, and 60-62.

If any additional fees are required or if the enclosed payment is insufficient, Appellant requests that the required fees be charged to Deposit Account 06-0916.

Table of Contents

I. Real Party in Interest

Gambro Lundia AB is the real party in interest in this appeal.

II. Related Appeals and Interferences

Appellant, Appellant's undersigned legal representative, and the assignee know of no appeals, interferences, or proceedings that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 4, 6-17, 20-25, 27-60, and 62 are currently pending in this Application. In the Final Office Action mailed on December 17, 2009, the Examiner rejected claims 4-17, 20-44, and 60-62 under 35 U.S.C. § 103(a). The final rejection of claims 4, 6-17, 20-25, 27-44, 60, and 62 is being appealed and a list of the claims on appeal is found in the attached Claims Appendix.

Claims 45-59 were withdrawn by the Examiner. Accordingly, claims 45-59 are not set forth in the Claims Appendix.

IV. Status of Amendments

All claim amendments, including Appellant's Amendment After Appeal filed on June 16, 2010, have been entered.

V. Summary of Claimed Subject Matter

A. Independent Claim 60

Independent Claim 60	Support from Specification for Independent Claim 60
60. A controller for a blood treatment equipment, said equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation of a treatment liquid,	Referring now to Figure 1 schematic drawing, reference numeral 1 refers generally to a blood treatment equipment, such as for instance hemodialysis equipment, comprising or associated with a controller 2, for instance a programmable controller. The equipment as shown is connected to a blood treatment unit 3, such as a hemodialyser, comprising a first or blood compartment 4 and a second or dialysate compartment 5 divided by a semi-permeable membrane 6. (Page 11, lines 16-22.)
the controller being configured to: receive one or more entries of measured information measured during the course of a treatment procedure,	The controller 2 is adapted to receive one or more entries of measured information measured during the course of a treatment procedure. (Page 14, lines 15-16.)
determine at time intervals during treatment: a parameter selected from the group consisting of an instantaneous clearance K_{Ti} measured at an elapsed treatment time T_i and a dialysance value DT_i measured at an elapsed treatment time T_i; and	The controller 1 is then programmed to calculate from the measured information (for instance from the value of the conductivity upstream and downstream the treatment unit) a value of at least a significant parameter indicative of the progress of an extracorporeal blood treatment carried out by the equipment. According to the invention the significant parameter is one chosen in the group comprising: - the actual dialysance D_{Ti} or clearance K_{Ti} of a blood treatment unit associated with the equipment for a specific solute after a time T_i elapsed from the beginning of the treatment. (Page 15, lines 16-24.)
an effective total dialysis dosage $K*T_{Ti}$ value which has been delivered at the elapsed treatment time T_i,	The controller 1 is then programmed to calculate from the measured information (for instance from the value of the conductivity upstream and downstream the treatment unit) a value of at least a significant parameter indicative of the progress of an extracorporeal blood treatment carried out by the equipment. According to the invention the significant parameter is one chosen in the group comprising: . . . - the dialysis dose $K*T_{Ti}$ achieved at the elapsed time T_i. (Page 15, line 16 - page 16, line 4.)

Independent Claim 60	Support from Specification for Independent Claim 60
wherein the controller is also configured to compare said calculated dialysis dose K^*T_{Ti} to at least a total dialysis dosage value K^*T_p to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment,	The controller according to the invention is adapted to receive one or more entries of measured information measured during the course of a treatment procedure, calculate from said measured information at least a significant parameter indicative of the progress of an extracorporeal blood treatment carried out by the equipment, compare said calculated significant parameter to at least a prescribed reference value for the same parameter, and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment. The significant parameter can be one chosen in the group comprising: . . . - the dialysis dose K^*T_{Ti} achieved at the elapsed time T_i. (Page 5, line 20 - page 6, line 13.)
the controller also being configured to determine at least one timing selected from the group consisting of an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value K_{Tp}.	After having started the treatment, the controller waits for a prefixed time, for instance 10 or 15 minutes, and then carries for the first time the loop shown in figure 2, loop cycle 20, which is then repeated at each successive time interval. More in detail, according to this embodiment, the controller is programmed for determining the estimated remaining treatment procedure time T_{tr} and/or the estimated total treatment time T_{tot} as a function of a calculated value of a significant parameter at time T_i. In other words the controller is able to modify the duration of the treatment if certain actual values of parameters deemed to be significant change during treatment. (Page 17, lines 6-12.)

B. Independent Claim 62

Independent Claim 62	Support from Specification for Independent Claim 62
62. A controller for a blood treatment equipment, said equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation of a treatment liquid,	Referring now to Figure 1 schematic drawing, reference numeral 1 refers generally to a blood treatment equipment, such as for instance hemodialysis equipment, comprising or associated with a controller 2, for instance a programmable controller. The equipment as shown is connected to a blood treatment unit 3, such as a hemodialyser, comprising a first or blood compartment 4 and a second or dialysat compartment 5 divided by a semi-permeable membrane 6. (Page 11, lines 16-22.)
the controller being configured to:	In particular, the controller according to the first embodiment receives (as a first step 21 of the loop cycle 20) the prescribed

Independent Claim 62	Support from Specification for Independent Claim 62
receive a reference value of a first prescribed parameter consisting of the total clearance value K_{Tp} to be achieved at the end of the treatment,	values for the dialysis dosage K_{Tp} and for the total weight loss W_{Lp} to be achieved at the end of the treatment. (Page 17, lines 15-17.)
receive a reference value of a second prescribed parameter consisting of a prescribed total weight loss W_{Lp} to be achieved at the end of the treatment,	In particular, the controller according to the first embodiment receives (as a first step 21 of the loop cycle 20) the prescribed values for the dialysis dosage K_{Tp} and for the total weight loss W_{Lp} to be achieved at the end of the treatment. (Page 17, lines 15-17.)
determine a prescribed rate R by dividing said total weight loss W_{Lp} to be achieved at the end of the treatment by said total dialysis dose value K_{Tp} to be achieved at the end of the treatment,	In detail the controller is programmed for determining a prescribed rate R by dividing said total weight loss W_{Lp} to be achieved at the end of the treatment by said total dialysis dose value K_{Tp} to be achieved at the end of the treatment, as shown in step 32. (Page 24, lines 14-17.)
determine at time intervals during treatment: a parameter selected from the group consisting of an instantaneous clearance K_{Ti} measured at an elapsed treatment time T_i and a dialysance value D_{Ti} measured at an elapsed treatment time T_i; and	In particular, the controller according to the first embodiment receives (as a first step 21 of the loop cycle 20) the prescribed values for the dialysis dosage K_{Tp} and for the total weight loss W_{Lp} to be achieved at the end of the treatment. Then, as second step 22, determines the instantaneous clearance K_{Ti} or dialysance value D_{Ti} corresponding to the conductivity or concentration measurements at treatment time T_i. (Page 17, lines 15-20.)
control the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{TI} at time T_i substantially equal to the product of said prescribed rate R by the instantaneous clearance K_{Ti} or instantaneous dialysance value D_{Ti} measured at treatment time T_i.	In detail the controller is programmed for determining a prescribed rate R by dividing said total weight loss W_{Lp} to be achieved at the end of the treatment by said total dialysis dose value K_{Tp} to be achieved at the end of the treatment, as shown in step 32. Then, in steps 33 and 34, the controller controls the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{TI} at time T_i substantially equal to the product of said prescribed rate R by the instantaneous clearance K_{Ti} or instantaneous dialysance value D_{Ti} measured at treatment time T_i. The loop is then concluded and the controller, as for the embodiment of figure 2, waits a time interval before sta[r]ting again loop 30 from the step 31 or directly from step 32, if no new prescribed values shall be considered. (Page 24, line 14 - page 25, line 3.)

VI. Grounds of Rejection to be Reviewed

A. The issue on appeal is whether the Examiner has sufficiently proven that claims 4-17, 20-44, and 60-62 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,258,027 to Sternby ("*Sternby*"); and

B. The issue on appeal is whether the Examiner has sufficiently proven that claims 4-17, 20-44, and 60-62 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,110,384 to Goux ("*Goux*").

VII. Argument

A. The Rejection of Claims 4-17, 20-44, and 60-62 Under 35 U.S.C. § 102 (b), as Anticipated by *Sternby* Should Be Reversed

Claims 4-17, 20-44, and 60-62 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Sternby*. Appellant respectfully submits that the Examiner has misinterpreted and misapplied the legal standard for claiming the configuration of a computer/controller. The Examiner has also failed to establish that *Sternby* discloses each and every element of the claims. Therefore, the Section 102 rejection over *Sternby* is improper and should be reversed.

1. Legal Standard

Anticipation is an exacting standard. Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference to anticipate the claim. *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). Implicit in a review of an Examiner's anticipation analysis is that the claim must first have been correctly construed to define the scope and meaning of each contested limitation. See, e.g., *In re Paulsen*, 30 F3d 1475, 1479 (Fed. Cir. 1994). ("To properly compare [an allegedly anticipatory prior art reference] with the claims at issue, we must construe the term 'computer' to ascertain its scope and meaning.") With respect to the pending claims, when the phrase "controller being configured to" is properly construed, it is apparent that *Sternby* does not anticipate the pending claims, as discussed in more detail below.

2. Claim Construction

In order to properly construe claim limitations, the PTO must "appl[y] to the verbiage of the proposed claims the broadest reasonable meaning of the words in their

ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The pending claims, and independent claims 60 and 62, in particular, require the the controller be configured to carry out specific steps relating to the operation of blood treatment equipment. This language means that the controller is programmed to carry out the specific steps recited in independent claims 60 and 62.

3. The Examiner Has Erred By Misinterpreting And Misapplying The Legal Standard For Claiming The Configuration Of A Computer/Controller

In the Advisory Action mailed June 1, 2010, the Examiner contends that the claims "are replete with functional and intended use language that does not structurally differentiate the controller." (Advisory Action at 2.) The Examiner further contends that

> [t]he controller of STERNBY is implicitly capable of manipulating the data from the sensor readings to determine the progress of the treatment (as shown above) and directing treatment based on sensor readings and data calculations (see claims 26-49 of STERNBY).

(*Id.*)

Appellant respectfully submits that the Examiner has committed error by misinterpreting and misapplying the standards for claiming the configuration/programming of a controller. Specifically, the Examiner has contended that the configuration of the claimed controller does not define structure, and therefore does not limit the claim. Appellant submits that refusal to give patentable weight to

limitations reciting the programming of a controller is directly contrary to precedent from the U.S. Court of Appeals for the Federal Circuit.

The U.S. Court of Appeals for the Federal Circuit has clearly stated that the programmed operations of a computer/controller define structure. Citing, *Application of Bernhart*, *In re Lowry* states that:

> [t]here is one further rationale used by both the board and the examiner, namely, that the provision of new signals to be stored by the computer does not make it a new machine, i.e. it is structurally the same, no matter how new, useful and unobvious the result.... To this question we say that if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged. The fact that these physical changes are invisible to the eye should not tempt us to conclude that the machine has not been changed. (Emphasis added.)

In re Lowry, 32 F.3d 1579, 1583 (Fed. Cir. 1994) (*citing In re Bernhart,* 57 C.C.P.A. 737, 417 F.2d 1395, 1400, 163 USPQ 611, 615-16 (CCPA 1969)). Accordingly, under *In re Lowry*, a claim's recitation of a controller that is configured or programmed to perform one or more functions *physically* distinguishes the claim from the prior art and must be considered.

To support his position, the Examiner states that an "apparatus must be distinguished from the prior art in terms of structure rather than function," which the Examiner contends was the holding of *In re Schreiber*. (*Advisory Action* at 2.) The Examiner relies on several other cases for similar propositions.

In re Schreiber and the other cases cited by the Examiner were related to substantially different factual situations than that of the instant case. For instance, none of the cases cited by the Examiner was related to computers/controllers. Rather, the

cases were generally related to claims reciting the "intended use" of known mechanical devices or claims related to the inherent features of a known product or process.[1] For example, the first case relied upon by the Examiner, *In re Schreiber*, related to an intended use of a known mechanical device. Claim 1 recited a "conical top" for "passing only several kernels of a popped popcorn." *In re Schreiber*, 128 F.3d 1473, 1475 (Fed. Cir. 1997). The court held that:

> Schreiber's contention that his structure will be used to dispense popcorn does not have patentable weight if the structure is already known, regardless of whether it has ever been used in any way in connection with popcorn.

Appellant submits that claiming the intended use of a known "conical top" is entirely different than claiming a controller programmed/configured to operate in a new and unobvious way. Claiming the programming/configuration of a controller is not "intended use" nor is it a recitation of the inherent characteristics of the prior art. Accordingly, the cases cited by the Examiner are inapposite.

The M.P.E.P. also supports Appellant's position that the Examiner misconstrued the "configured to" language of independent claims 60 and 62, and erroneously labeled this language as "intended use language."

M.P.E.P.2111.04 states:

> Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim a particular structure. However, examples of claim language,

1 *Ex parte Masham* dealt with a chamber and a stationary mixing means (*see, e.g., Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987); *Ex parte Thibault* dealt with a "reservoir" (*see e.g., Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969)); and *In re Best* dealt with claiming of inherent features of a known element or process step (*see. e.g., In re Best*, 562 F.2d 1252 (GGPA 1977).

although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

(A) "adapted to" or "adapted for" clauses;
(B) "wherein" clauses; and
(C) "whereby" clauses.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In *Hoffer v. Microsoft Corp.*, 405 F.3d 1329, 74 USPQ2d 181, 1483 (Fed. Cir. 2005), the court held that when a "'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Id.* However, the court noted (quoting Minton v. Nat'l Ass'n of Securities Dealers, Inc., 336 F.3d, 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a "'whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.'" Id.<

Accordingly, the M.P.E.P. requires the Examiner to analyze the facts of a particular application and claim language, instead of applying a general per se rule. Independent claims 60 and 62 of the instant application limit the claims by reciting a "controller being configured to" perform specific operations.. The "configured to" language recited in those claims imposes structure on the claims and requires the controller to be programmed to carry out the recited claim steps. The claim language is not "intended use" as contended by the Examiner, but rather imposes significant structural limitations on the claimed controller.

Moreover, while the language in the pending claims is "structural" and not "functional," the Examiner's treatment of alleged "functional" language in a claim is similarly erroneous. In fact, it is well established that an "[a]pplicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought." M.P.E.P. § 2173.01.

> A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.

M.P.E.P. § 2173.05(g). Accordingly, when the claim language is properly interpreted, be it "functional" or not, the Examiner has erred by not fully evaluating and considering each and every element of the pending claims.

In the Advisory Action the Examiner also contends that:

> [i]n any case, the mathematical expression[] for calculating a parameter is not a patentable limitation in an apparatus as it does not structurally distinguish the claimed invention from the apparatus of STERNBY.

(Advisory Action at 2.) As noted above, the claimed controller does in fact distinguish from the prior art in terms of structure rather than function or intended use as explained in *In re Lowry,* and as provided in the M.P.E.P. Furthermore, Appellant disagrees with the Examiner's characterization of the pending claims.

The claims do not simply recite mathematical expressions for calculating a parameter. For example, independent claim 60 recites, among other things, a controller being configured to: receive one or more entries of measured information; determine a parameter at time intervals during treatment; and generate at least one output control signal. Independent claim 62 recites, among other things, a controller being configured to: receive a reference value; determine a parameter at time intervals during treatment; and control the rate of fluid removal. Accordingly, the claims do not simply recite mathematical expressions, but rather a controller that is programmed to operate in a specific way.

For at least the aforementioned reasons, the Examiner's refusal to examine and give patentable weight to the limitations of the claims is clear error as shown by Federal Circuit law, as well as the M.P.E.P. Accordingly, the Section 102 rejection should be reversed and the claims reconsidered by the Examiner.

4. The Section 102 Rejection Is Deficient Because *Sternby* Does Not Disclose Each And Every Element Of The Claims.

a) Independent Claim 60

The Examiner has committed error by rejecting independent claim 60 as being anticipated by *Sternby*. *Sternby* does not disclose each and every element of the claim, and therefore, the Section 102 rejection should be reversed.

Sternby discloses a urea monitor 18. (*See* col. 11, lines 13-14.) The urea monitor 18 of *Sternby* may measure the urea concentration to:

> determin[e] parameters of the dialysis as it progresses. These parameters are used for assessing the dialysis treatment on-line to determine the efficiency, the delivered dose, pre and post total urea masses in the body, the urea generation rate, the volume of distribution of urea in the body (for example by taking a blood sample for determining the urea concentration in the blood), and still further parameters and variables.

(Col. 12, lines 30-38.) In other words, *Sternby* discloses a device for monitoring and/or determining a number of parameters to assess a dialysis treatment. *Sternby*, however, does not disclose a "controller" configured to "compare [a] calculated dialysis dose K^*T_{Ti} to at least a total dialysis dosage value K^*T_p to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment," as recited in independent claim 60.

In the Final Office Action, the Examiner stated that

> STERNBY discloses a blood treatment (Fig. 1) with a semi-permeable membrane (3) with first and second compartments for blood and treatment liquid (C10/L43-47) and a **controller (17)**.

(Final Office Action at 3, emphasis added.) *Sternby* discloses that computer 17 is configured to control "[t]he valves and the pumps . . . as schematically shown by several lines in FIG. 1." (Col. 10, lines 61-63.) *Sternby* also discloses that computer 17 may "provide concentration values c_d as well as values of the total mass of urea, U, removed during the treatment as the integral of Q_d*c_d." (Col. 11, lines 28-30.) However, *Sternby* does not disclose that computer 17 is configured to "compare [a] calculated dialysis dose $K*T_{Ti}$ to at least a total dialysis dosage value $K*T_p$ to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment," as recited in independent claim 60.

In fact, in the advisory action, the Examiner implicitly concedes that *Sternby* does not disclose such a controller. The Examiner states that "[t]he controller of STERNBY is implicitly **capable** of manipulating the data from the sensor readings to determine the progress of the treatment (as shown above) and directing treatment based on sensor readings and data calculations." (Advisory Action at 2, emphasis added.) In other words, the Examiner has conceded that *Sternby* does not in fact disclose a controller configured to "manipulate" the data and "direct" the treatment as recited in independent claim 60, but rather *could* be programmed to do so. The Examiner's position is completely untenable. Based on the Examiner's reasoning, any reference disclosing a device for monitoring blood treatment having a controller would anticipate the pending

claims, regardless of the disclosed function of the controller. As noted above, a Section 102 rejection requires that every limitation of a claim must identically appear in a single prior art reference to anticipate the claim. See, e.g., *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). *Sternby* does not satisfy this requirement.

Appellant further submits that the Examiner has committed error because *Sternby* does not disclose a controller configured to determine "at least one timing selected from the group consisting of an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value KT_p," as recited in independent claim 60.

For at least the aforementioned reasons, the Examiner committed error by rejecting independent claim 60 as being anticipated by *Sternby*. Accordingly, Appellant respectfully requests the reversal of the rejection of independent claim 60 under 35 U.S.C. § 102(b) as being anticipated by *Sternby*.

b) Independent Claim 62

The Examiner has committed error by rejecting independent claim 62 as being anticipated by *Sternby*. *Sternby* does not disclose each and every element of the claim, and therefore, the Section 102 rejection should be reversed.

As noted above, *Sternby* discloses a device for monitoring and/or determining a number of parameters to assess a dialysis treatment. *Sternby*, however, does not disclose a "controller" configured to "control the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{Ti} at time T_i substantially equal to the product of said prescribed rate R

by the instantaneous clearance K_{Tt} or instantaneous dialysance value D_{Ti} measured at treatment time Ti," as recited in independent claim 62.

For at least the aforementioned reason, the Examiner committed error by rejecting independent claim 62 as being anticipated by *Sternby*. Accordingly, Appellant respectfully requests the reversal of the rejection of independent claim 62 under 35 U.S.C. § 102(b) as being anticipated by *Sternby*.

c) Dependent Claims

The rejection of claims 4, 6-17, 20-25, and 27-44 should be overturned at least due to the dependence of each of these claims from independent claim 60.

The rejection of the dependent claims should also be overturned due the claims' additional recitations of patentable subject matter. Appellant notes that the Examiner has rejected many of the dependent claims generically without addressing the recited limitations. For example, claim 9 recites "setting of fluid removal rate UF from said second compartment for achieving a prescribed total weight loss WLp substantially at the same time as the prescribed total dialysis dosage value KTp is achieved." This feature is neither discussed by the Office Action nor is it disclosed by the cited reference. Accordingly, Appellant submits that the Examiner's failure to properly consider these elements was clear error, and the rejection of the dependent claims should be overturned for at least these reasons.

B. <u>The Rejection Of Claims 4-17, 20-44, And 60-62 Over *Goux* Should Be Reversed</u>

Claims 4-17, 20-44, and 60-62 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Goux*. Appellant respectfully submits that the Examiner has misinterpreted and misapplied the legal standard for claiming the configuration of a

computer/controller. The Examiner has also failed to establish that *Goux* discloses each and every element of the claims. Therefore, the Section 102 rejection over *Goux* is improper and should be reversed.

1. The Examiner Has Erred By Misinterpreting And Misapplying The Legal Standard For Claiming The Configuration Of A Computer/Controller

Similar to the discussion above with respect to the *Sternby*, the Examiner has misinterpreted and misapplied the standards for claiming the configuration/programming of computers/controllers. In the Section 102 rejection over *Goux*, the Examiner makes similar arguments regarding the claims' alleged functional and intended use language. (*See, e.g.*, Final Office Action at 6-7.) However, as discussed above, the Examiner's refusal to examine and give patentable weight to the limitations of the claims is clear error under Federal Circuit law. Accordingly, the Section 102 rejection should be reversed and the claims reconsidered by the Examiner.

1. The Section 102 Rejection Is Deficient Because *Goux* Does Not Disclose Each And Every Element Of The Claims.

a) Independent Claim 60

The Examiner has committed error by rejecting independent claim 60 as being anticipated by *Goux*. *Goux* does not disclose each and every element of the claim, and therefore, the Section 102 rejection should be reversed.

Goux is directed to a method "for determining a parameter (D, K, Kt/v, Cbin) indicative of the effectiveness of an extracorporeal blood treatment carried out using a membrane exchanger." (Abstract.) *Goux* discloses a computing and control unit 30. The control unit is:

> connected to a screen 31 and to a keyboard 32 via which the user inputs various set values to it, namely flow rate set values (blood flow rate Qb, dialysis liquid flow rate Qd), conductivity set values used for preparation of the dialysis liquid, a treatment duration set value T and a weight loss set value WL. Moreover, the computing and control unit 30 receives information sent out by the measurement devices of the system, such as the flow meters 21, 27, the conductivity probes 17, 20, 23, 25, and the urea-measuring device 28. It controls, depending on the instructions received and on programmed algorithms and operating modes, the devices for driving the system, such as the pumps 6, 16, 19, 22, 26, 29.

(Col. 5, lines 25-39.)

Goux discloses performing a number of steps, including:

1. "Creation of a perturbation in the exchange conditions established in the haemodialyser 1." (Col. 6, lines 23-34.)
2. "Determination of a quantity indicative of the variation imposed on the chosen characteristic of the dialysis liquid." (Col. 7, lines 41-42.)
3. "Determination of a quantity indicative of the variation in the characteristic downstream of the haemodialyser 1, as it appears, deformed by the exchanges having taken place in the haemodialyser 1." (Col. 9, lines 50-53.) and
4. "Calculation of a parameter indicative of the effectiveness of the treatment administered." (Col. 11, lines 1-2.)

Regarding step 4, *Goux* discloses that the control unit may be configured to calculate the dialysance. (*See, e.g.*, col. 11, lines 8-15.)

In other words, *Goux* discloses a system configured to create a perturbation, measure the results of the perturbation, and use the measurements to calculate a parameter indicative of the effectiveness of the treatment. *Goux* does not disclose, however, a controller configured to "compare [a] calculated dialysis dose K^*T_{Ti} to at least a total dialysis dosage value K^*T_p to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for

automatically controlling one or more operations performed by the equipment," as recited in independent claim 60. Additionally, *Goux* does not disclose a controller configured to determine "at least one timing selected from the group consisting of an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value KT_p," as recited in independent claim 60. Accordingly, *Goux* does not disclose each and every one of the claimed features.

For at least the aforementioned reasons, the Examiner committed error by rejecting independent claim 60 as being anticipated by *Goux*. Accordingly, Appellant respectfully requests the reversal of the rejection of independent claim 60 under 35 U.S.C. § 102(b) as being anticipated by *Goux*.

b) Independent Claim 62

The Examiner has committed error by rejecting independent claim 62 as being anticipated by *Goux*. *Goux* does not disclose each and every element of the claim, and therefore, the Section 102 rejection should be reversed.

As noted above, *Goux* discloses *Goux* discloses a system configured to create a perturbation, measure the results of the perturbation, and use the measurements to calculate a parameter indicative of the effectiveness of the treatment. *Goux*, however, does not disclose a "controller" configured to "control the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{Ti} at time T_i substantially equal to the product of said prescribed rate R by the instantaneous clearance K_{Tt} or instantaneous dialysance value D_{Ti} measured at treatment time Ti," as recited in independent claim 62.

For at least the aforementioned reasons, the Examiner committed error by rejecting independent claim 62 as being anticipated by *Goux*. Accordingly, Appellant respectfully requests the reversal of the rejection of independent claim 62 under 35 U.S.C. § 102(b) as being anticipated by *Goux*.

c) Dependent Claims

The rejection of claims 4, 6-17, 20-25, and 27-44 should be overturned at least due to their dependence from independent claim 60.

The rejection of the dependent claims should also be overturned due the claims additional recitations of patentable subject matter. As noted above, the Examiner has rejected many of the dependent claims generically without addressing the recited limitations. For example, claim 9 recites "setting of fluid removal rate UF from said second compartment for achieving a prescribed total weight loss WLp substantially at the same time as the prescribed total dialysis dosage value KTp is achieved." This feature is neither discussed by the Office Action nor is it disclosed by the cited reference. Accordingly, Appellant submits that the Examiner's failure to properly consider these elements was clear error, and the rejection of the dependent claims should be overturned for at least these reasons.

C. Conclusion

For the reasons given above, pending claims 4, 6-17, 20-25, 27-60, and 62 are allowable, and Appellant respectfully requests reversal of the outstanding rejections.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith,

including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: September 14, 2010

By: */Aaron L. Parker/*
Aaron L. Parker
Reg. No. 50,785

VII. Claims Appendix

1-3. (Canceled)

4. (Previously Presented) A controller according to claim 60, wherein the controller generates the output control signal responsive to said comparison for automatically controlling a fluid removal rate from said second compartment.

5. (Canceled)

6. (Previously Presented) A controller according to claim 60, wherein said controller is programmed for determining the estimated remaining treatment procedure time T_{tr} as a function of said total dialysis dosage value KT_p, the effective total dialysis dosage KT_{ti} achieved by time T_i, and of the instantaneous clearance K_{Ti} or dialysance value D_{Ti} measured at treatment time T_i.

7. (Previously Presented) A controller according to claim 60, wherein said controller is programmed for determining the estimated total treatment time T_{tot} as a function of said total dialysis dosage value KT_p, of the effective total dialysis dosage KT_i achieved by time T_i, and of the elapsed treatment time T_i.

8. (Previously Presented) A controller according to claim 6, wherein said controller, at each time interval, is programmed for updating the estimated total

treatment time T_{tot} as sum of the elapsed treatment time T_t and of the estimated value of the remaining treatment procedure time T_{tr}.

9. (Previously Presented) A controller according to claim 6 or 7, wherein said prescribed parameter also comprises a prescribed total weight loss WL_p to be achieved at the end of the treatment, said controller being programmed for performing the following further steps at time intervals during treatment:

determining of an actual measured total weight loss WL_{Ti} achieved by time T_i, and

setting of fluid removal rate UF from said second compartment for achieving a prescribed total weight loss WL_p substantially at the same time as the prescribed total dialysis dosage value KT_p is achieved.

10. (Previously Presented) A controller according to claim 9, wherein the controller is programmed for controlling, on an ongoing basis, the fluid removal rate as a function of the estimated remaining treatment procedure time T_{tr} or of estimated total treatment time T_{tot}.

11. (Previously Presented) A controller according to claim 10, wherein said controlling comprises setting of the fluid removal rate UF_{Ti} at time T_i equal to the prescribed total weight loss WL_p less the measured weight loss WLT_i at time T_i, divided by the estimated remaining treatment time T_r, according to the formula:

$$UF_{Ti} = \frac{WL_p - WL_{Ti}}{T_{tr}}$$

12. (Previously Presented) A controller according to claim 10, wherein said controlling step comprises setting of the fluid removal rate UFT_i at time T_i equal to the prescribed total weight loss WL_p less the measured weight loss WL_{Ti} at time T_i, divided by a difference between the estimated total treatment time T_{tot} and the elapsed treatment time T_t according to the formula: $UF_{Ti} = \frac{WL_p - WL_{Ti}}{T_{tot} - T_i}$

13. (Previously Presented) A controller according to claim 60, wherein the controller is programmed for recalculating and updating at regular time intervals during treatment the estimated total treatment time T_{tot} and/or the estimated remaining treatment time T_{tr}, on the basis of the most recent value or values of instantaneous clearance K_{Ti} or dialysance D_{Ti}.

14. (Previously Presented) A controller according to claim 60, wherein the controller is programmed for recalculating and updating at regular time intervals during treatment the effective total dialysis dosage KT_{Ti} value, which has been delivered at the elapsed effective treatment time T_i.

15. (Previously Presented) A controller according to claim 60, wherein the instantaneous clearance value K_{Ti} or instantaneous dialysance value D_{Ti} is determined at treatment time T_i, by a method comprising the following sub-steps:

sending at least a first liquid through the second compartment of the treatment unit,

sending at least a second liquid through the second compartment of the treatment unit, the second liquid having conductivity or concentration for at least a solute different from that of the first liquid,

measuring the conductivity or concentration values of said substance in the treatment liquid downstream the treatment unit at least for both said first and for said second liquid, and

calculating the instantaneous clearance KT_i or instantaneous dialysance value D_{Ti} at least as a function of said measured conductivity or concentration values.

16. (Previously Presented) A controller according to claim 60, wherein the effective total dialysis dosage KT_{Ti} value, which has been delivered at the determined effective treatment time T_i, is calculated as an integration over time of effective instantaneous clearance K_{Ti} or instantaneous dialysance D_{Ti} values determined at the various regular time intervals T_i.

17. (Previously Presented) A controller according to claim 60, wherein the effective total dialysis dosage KT_i value, which has been delivered at the effective treatment time T_i, is calculated as the product of the treatment time T_i by a mean value of effective instantaneous clearance K_{Ti} or of instantaneous dialysance D_{Ti} values determined at the various regular time intervals T_i.

18-19. (Canceled)

20. (Previously Presented) A controller according to claim 60, wherein said controller, at each time interval, is programmed for:

calculating a sum of the elapsed treatment time T_i with the calculated value of the remaining treatment procedure time T_{tr},

comparing said sum with a minimum treatment time T_{min} and with a maximum treatment time T_{max},

setting a total treatment time T_{tot} equal to the minimum treatment time T_{max}, if said sum is less then the minimum treatment time T_{min},

setting a total treatment time T_{tot} equal to the maximum treatment time T_{max}, if said sum is more then the minimum treatment time T_{max},

setting a total treatment time T_{tot} equal to said sum if the sum is neither less then the minimum treatment time T_{min} nor more then the minimum treatment time T_{max}.

21. (Previously Presented) A controller according to claim 20, wherein said prescribed parameter also comprises a prescribed total weight loss WL_p to be achieved at the end of the treatment, said controller being programmed for performing the following further steps at time intervals during treatment:

determining of an actual measured total weight loss WL_{Tt} achieved by time T_t, and

setting of fluid removal rate from said second compartment for achieving a prescribed total weight loss WL_p at said total treatment time T_{tot}.

22. (Previously Presented) A controller according to claim 21, wherein the controller is programmed for controlling, on an ongoing basis, the fluid removal rate UF_{Ti} at time T_i as a function of the total treatment time T_{tot} by setting the UF_{Ti} fluid removal rate at time T_i equal to the prescribed total weight loss WL_p less the measured weight loss WL_{Ti} at time T_i, divided by the difference between the calculated total treatment time T_{tot} and the elapsed treatment time T_i, according to the formula:

$$UF_{Ti} = \frac{WL_p - WL_{Ti}}{T_{tot} - T_i}$$

23. (Previously Presented) A controller according to claim 21, wherein the controller is programmed for recalculating and updating the total treatment time T_{tot} and/or the remaining treatment time T_{tr} at regular time intervals during treatment, on the basis of the last or most recent instantaneous measured value or values of clearance K_{Ti} or dialysance D_{Ti}.

24. (Previously Presented) A controller according to claim 21, wherein the controller is programmed for recalculating and updating at regular time intervals during treatment the effective total dialysis dosage KT_{Ti} value which has been delivered at the elapsed effective treatment time T_i.

25. (Previously Presented) A controller according to claim 21, wherein the effective total dialysis dosage K_{Ti} value, which has been delivered at the determined effective treatment time T_i, is calculated as an integration over time of effective

instantaneous dialysis dosage values DT_i determined at the various regular time intervals T_i.

26. (Canceled).

27. (Previously Presented) A controller according to claim 60, wherein the prescribed reference value comprises a patient blood conductivity or concentration target Cp_{end} to be achieved, said controller being programmed for changing, if necessary, at each time interval, the conductivity or concentration of the treatment liquid entering the second compartment in order to have blood conductivity or concentration for a substance reaching said conductivity or concentration target Cp_{end} on or before said estimated total treatment time T_{tot}.

28. (Previously Presented) A controller according to claim 9, wherein the prescribed reference value comprises a patient blood conductivity or concentration target Cp_{end} to be achieved, said controller being programmed for changing, if necessary, at each time interval, the conductivity or concentration of the treatment liquid entering the second compartment in order to have blood conductivity or concentration for a substance reaching said conductivity or concentration target Cp_{end} on or before said estimated total treatment time T_{tot}.

29. (Previously Presented) A controller according to claim 60, wherein the prescribed reference value comprises a patient blood conductivity or concentration

target Cp_{end} to be achieved, said controller being programmed for performing the following steps at each time interval t_i during at least a part of said treatment:

determining an interval target blood conductivity or concentration Cp_i for the patient's blood, relating to a elapsed time T_i, and

modifying, if necessary, the conductivity or concentration for a substance C_d of treatment liquid entering the second compartment to have the patient plasmatic conductivity reaching the interval target Cp_i.

30. (Previously Presented) A controller according to claim 29, wherein said modifying of treatment liquid conductivity or concentration C_d comprises the following sub-steps:

determining a calculated value C_{di} of the conductivity or concentration for a substance C_d as a function of the interval target C_{pi} and of the measured instantaneous dialysance or clearance D_i or K_i for time T_i,

bringing the conductivity or concentration for a substance C_d of treatment liquid entering the second compartment to said calculated value C_{di}.

31. (Previously Presented) A controller according to claim 30, wherein the said determining step uses the following formula:

$$C_d = C_{di} = \frac{C_{Pi} - C_{Pi-1} e^{-\frac{Di}{V_0}(Ti - Ti-1)}}{1 - e^{-\frac{Di}{V_0}(Ti - Ti-1)}}$$

wherein V_0 represents the urea distribution volume for the patient.

32. (Previously Presented) A controller according to claim 30, wherein the said determining step uses the following formula:

$$C_d = C_{di} = \frac{C_{Pi} - C_{Pi-1} e^{-\frac{Ki}{V_0}(Ti - Ti-1)}}{1 - e^{-\frac{Ki}{V_0}(Ti - Ti-1)}}$$

wherein V_0 represents the urea distribution volume for the patient.

33. (Previously Presented) A controller according to claim 29, wherein the controller is programmed for calculating said interval target blood conductivity or concentration Cp_i for the patient's blood relating to a time interval T_i, according to the following steps:

evaluating if the elapsed treatment time T_i is more or less of a prescribed value T_p,

assigning as interval target blood $Cp_i = Cp_{end} + A$, wherein A is a positive value, if T_i less than T_p, and

assigning as interval target blood $Cpi = Cp_{end}$, if T_i more than or equal to T_p.

34. (Previously Presented) A controller according to claim 33, wherein the prescribed value T_p is less than T_{tot}.

35. (Previously Presented) A controller according to claim 34, wherein the prescribed value T_p is equal to T_{tot} reduced by one hour.

36. (Previously Presented) Blood treatment equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation of a treatment liquid, and a controller according to claim 60.

37. (Original) Equipment according to claim 36, comprising measuring means connected to the controller for measuring at least one of:

conductivity of the of the treatment liquid downstream the treatment unit; or

concentration of a substance in the treatment liquid downstream the treatment unit.

38. (Original) Equipment according to claim 36, comprising measuring means for measuring at least one of:

conductivity of the of the treatment liquid upstream the treatment unit; or

concentration of a substance in the treatment liquid upstream the treatment unit.

39. (Original) Equipment according to claim 37, comprising measuring means for measuring comprises a conductivity cell or an ion selective sensor or a urea sensor, operating on a conduit downstream the treatment unit.

40. (Original) Equipment according to claim 38, comprising measuring means for measuring comprises a conductivity cell or an ion selective sensor, operating on a conduit upstream the treatment unit.

41. (Previously Presented) Equipment according to claim 36 also including entry means for entering prescribed reference value or values for the significant parameter or parameters.

42. (Original) Equipment according to claim 36, comprising a variable speed ultrafiltration pump, in which the controller is programmed to generate a control signal to automatically control the fluid removal rate from said second compartment by controlling the variable speed ultrafiltration pump.

43. (Original) Equipment according to claim 36, wherein the controller is associated with an alert device, and the controller is programmed to activate said alert device if the expected treatment procedure time or remaining hemodialysis treatment time are not within a prefixed range.

44. (Previously Presented) Equipment according to claim 36, in which the controller is associated with a display screen adapted to display at the time intervals T_i one or more of the values selected from the group consisting of:

remaining time T_{tr},

total treatment time T_{tot},

clearance of dialysance measurements at the elapsed time T_i,

achieved dialysis dosage KT_{Ti} after T_i time,

achieved weight loss WL_{Ti} after T_i time,

achieved patient's conductivity after T_i time,

prescribed value for more of the significant parameters, and

a value proportional to one or more of the above values.

45-59. (Withdrawn)

60. (Previously Presented) A controller for a blood treatment equipment, said equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation of a treatment liquid,

the controller being configured to:

receive one or more entries of measured information measured during the course of a treatment procedure,

determine at time intervals during treatment:

a parameter selected from the group consisting of an instantaneous clearance K_{Ti} measured at an elapsed treatment time T_i and a dialysance value D_{Ti} measured at an elapsed treatment time T_i; and

an effective total dialysis dosage $K*T_{Ti}$ value which has been delivered at the elapsed treatment time T_i,

wherein the controller is also configured to compare said calculated dialysis dose $K*T_{Ti}$ to at least a total dialysis dosage value $K*T_p$ to be achieved at the end of the treatment and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the

equipment, the controller also being configured to determine at least one timing selected from the group consisting of an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value KT_p.

61. (Canceled)

62. (Previously Presented) A controller for a blood treatment equipment, said equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation of a treatment liquid,

the controller being configured to:

receive a reference value of a first prescribed parameter consisting of the total clearance value K_{Tp} to be achieved at the end of the treatment,

receive a reference value of a second prescribed parameter consisting of a prescribed total weight loss W_{Lp} to be achieved at the end of the treatment,

determine a prescribed rate R by dividing said total weight loss W_{Lp} to be achieved at the end of the treatment by said total dialysis dose value K_{Tp} to be achieved at the end of the treatment,

determine at time intervals during treatment:

a parameter selected from the group consisting of an instantaneous clearance K_{Ti} measured at an elapsed treatment time T_i and a dialysance value D_{Ti} measured at an elapsed treatment time T_i; and

control the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{Ti} at time T_i substantially equal to the product of said prescribed rate R by the instantaneous clearance K_{Tt} or instantaneous dialysance value D_{Ti} measured at treatment time Ti.

VIII. Evidence Appendix

No evidence is being relied upon herein by Appellant.

IX. Related Proceedings Appendix

No related proceeding decisions are relied upon herein by Appellant.